

Member Alert

Changes coming to Advertising pre-approvals process

Brand name assistance for Labels – TGA Consent Applications Announced

Changes coming to advertising pre-approvals process

As foreshadowed in [the reforms to the advertising framework](#), the pre-approval process for specific types of advertisements, will be abolished by 1 July 2020. The pre-approval process for advertisements for complementary medicines in certain specified media such as print media has to date been handled by Complementary Health Care Council of Australia (CHCA).

New arrangements

CMA has been negotiating with TGA regarding the transition process with the [TGA announcing](#) that CHCA will no longer accept any new applications for pre-approval from 14 November 2019. CHCA intends to finalise all existing applications by 27 January 2020.

The TGA states that they will be providing arrangements to replace CHC's services for applications from 14 November 2019, however the details of these cannot be made available until the Government has approved the amended Therapeutic Goods Regulations to support alternate arrangements.

Until these alternative arrangements have been made, any applications that need to be made between 14 November and the commencement date of the new regulations, can be made directly to the TGA and will be forwarded to the new service provider once arrangements are in place.

Key dates for sponsors (with .ics links to add to your calendar)

[14 November 2019](#): CHC will stop receiving pre-approval applications. At this time, it is recommended applications are held, however, applications can be sent to the TGA who will forward to the new service provider.

14 November - December 2020: Amending regulations to be finalised to support alternate arrangements, which are yet to be announced.

December 2020 – new advertising arrangements in place (to be announced).

[6 January 2020](#) – for applications received prior to 14 November, no extensions will be granted beyond 6 January 2020

[20 January 2020](#) - Last date for correspondence to be received by CHCA if it is to be considered in a final decision for remaining applications.

27 January 2020 - Final decisions for all remaining applications made by CHCA

[27 January 2020](#) - Make sure all invoices for these applications have been paid before 27 January 2020. Failure to pay these fees by this date will be grounds for refusal of applications.

[1 July 2020](#) – Advertising Pre-Approval scheme ceases operation (last day 30 June 2020).

The table below, extracted from the TGA website, clarifies actions that need to be taken from now until the new arrangements are in place (December 2020).

If you...	Then...
<p>Are seeking a pre-approval decision for a complementary medicine advertisement in print, cinema, billboards or other public displays before early December</p>	<p>Lodge your application with CHC as soon as possible.</p> <p>High quality applications for compliant advertisements and other straight-forward decisions (e.g. re-approval of an expired approval with no changes) will be given priority and decided quickly.</p> <p>Poorer applications may end in refusals as time runs out for CHC to make its final decisions in January. After 20 January 2020, decisions on applications with CHC will be made on the information available at the time of the decision. This will include refusal where the requirements for approval have not been satisfied. Applicants will still have the right to request a review of the decision (Regulations 5M and 5P).</p> <p>Don't book your advertising space until you receive an approval. <u>Subscribe to the TGA Advertising email list</u> to be notified of the alternate arrangements for your future applications.</p>
<p>Are considering applying between 14 November and the start of the new arrangements (late November/early December), the TGA recommend that you wait for the start of the new arrangements.</p>	<p>If you must apply between 14 November and the start of new arrangements, you can lodge your application with the TGA via email to advertising.preapproval@tga.gov.au.</p> <p>Your application will be held and forwarded for consideration under the new arrangements.</p> <p>Ensure you use the current <u>application form</u>. Note that this will change at the start of the new arrangements.</p>
<p>Are considering an advertisement that will need pre-approval but you don't need to apply before the start of the new arrangements</p>	<p><u>Subscribe to the TGA Advertising email list</u> to be notified of the new arrangements.</p> <p>Wait for the new arrangements to start.</p> <p>Lodge your application as directed.</p> <p>Ensure you use the most recent version of the <u>application form</u>.</p>
<p>Have lodged a pre-approval application with CHC before 14 November 2019</p>	<p>Applications received prior to 14 November 2019 will be considered and a decision made by CHC.</p> <p>No extensions will be granted beyond 6 January 2020.</p> <p>Ensure all correspondence with CHC has been finalised by 20 January 2020.</p> <p>Make sure you have paid all invoices for these applications before 27 January 2020. Failure to pay these fees will be grounds for refusal of the applications if not received in time.</p> <p>You should <u>subscribe to the TGA Advertising email list</u> to be notified of the new arrangements for any future applications.</p>

Brand name assistance for Labels – TGA Consent Applications Announced

CMA are pleased to announce that through CMA advocacy, working with direct member involvement, the TGA have announced the specialised application process that is intended to provide relief to sponsors whose pre-existing, reasonably presented brand logos/trademarks on medicine labels would be adversely affected by a particular part of the TGO 92. The specialised application process provided under Section 14/14A of the Act is designed to be practical to achieve and relatively low cost. It will help sponsors during the next few years to maintain some existing elements of brand logos/trademarks, which allows the TGA additional time for a consultation on TGO 92 in 2021 to examine the possibility of more permanent options for additional branding flexibility for non-prescription medicine sponsors. Therefore any consent provided will be active until **1 September 2021**.

Background

The TGO 92 labelling order includes changes to the requirements related to the presentation of the name of medicines on product labels. The name of the medicine is defined in section 6 of TGO 92 as **the name that appears on the ARTG certificate**. This may mean that certain complementary and OTC medicines may be non-compliant with subsection 9(2) as a result of inclusion of brand names, logos and trademarks on labels and packaging, that could constitute the name of the medicine.

Requests to supply goods with distinguishing marks that do not comply with TGO 92

If your medicine contains a “**distinguishing mark**” – a registered trademark, a graphic image, icon or logo, a brand name, slogan or tagline – and this distinguishing mark is used by the sponsor to uniquely identify a product range of therapeutic goods – the TGA has established an interim process for these medicines to request consent for non-compliance with section 9(2). This has to be made by application for each medicine by using the forms published [here](#).

The TGA have published a range of matters that would be eligible for consent, and also cases where consent is likely to be refused. These are outlined on the [TGA website](#).

The duration of consent will be limited to **1 September 2021** to allow time for potential amendments to TGO 92 to be considered and finalised.

If your medicine name, including any distinguishing marks, are already compliant with TGO 92, you do not need to consider this process.

If you are unsure, it is possible to submit an application as a precaution. If you have read all the information and still wish to discuss anything to help clarify the issue or process before contacting the TGA, please arrange a short teleconference with CMA by emailing Lucy.Lang@cmaustralia.org.au. Prior technical alerts relating to the naming issue are available [here \(Apr 2019\)](#) and [here \(Sep 2019\)](#).

Members are encouraged to forward any identified issues to technical@cmaustralia.org.au for attention by the Committee Secretariat.



ENDS